510(K) SUMMARY

SEP 19 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: K121224

1. Submitter's Identification:

TaiDoc Technology Corporation
3F, 5F, No.127, Wugong 2nd Rd., Wugu District, New Taipei City, 24888, Taiwan

Correspondent:
Linda Ko
Regulatory Affairs Specialist
Tel: +886-2-6625-8188 #1158
Fax: +886-2-6625-0288
Email: kolinda@taidoc.com.tw

Prepared date: April 20th, 2012

2. Device name:

Proprietary name: Genesis Health Technologies Blood Glucose Monitoring System, model TD-4123
Genesis Health Technologies control solutions

Regulatory information:

A. Regulation section: 21 CFR 862.1345 Glucose Test System
21 CFR 862.1660 Quality control material (assayed and unassayed).

B. Classification: Class II, Class I

C. Product Code: LFR, Glucose Dehydrogenase, Glucose
NBW, System, Test, Blood Glucose, Over the Counter
JJX, single (specified) analyte controls (assayed and unassayed)

D. Panel: Clinical Chemistry (75)

3. Intended Use:

For single use device

The Genesis Health Technologies Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood (from the finger, palm, forearm and upper arm). It is intended for use by people with diabetes at home as an aid to monitoring the effectiveness of diabetes control. It should not be used for the diagnosis of or screening for diabetes, or testing on neonates.

This system is intended to be used by a single person and should not be shared.

The Genesis Health Technologies test strips are for use with the Genesis Health Technologies meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from fingertips, palm, forearm and upper arm.

Alternative site testing should be done only during steady–state times (when glucose is not changing rapidly).

The Genesis Health Technologies control solutions are for use with the Genesis Health Blood Glucose meter and test strips to check that the meter and test strips are working together properly and that the test is performing correctly.

4. Device Description:

   The system consists of three main products: the meter, test strips, and control solutions. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results.

5. Substantial Equivalence Information:
   A. Predicate device name: U-RIGHT TD-4252 Blood Glucose Monitoring System, model TD-4252
   B. Predicate K number: K101631
   C. Comparison with predicate:

   The modified Genesis Health Technologies Blood Glucose Monitoring System has the following similarities to the predicate device:

   - Same operating principle.
   - Same fundamental scientific technology.
   - Incorporate the same basic circuit design.
   - Incorporate the same materials.

- Same shelf life.
- Packaged using the same materials.
- Manufactured by the same process.

The modifications encompass:

- Modifications in the physical appearance
- Software modifications of the glucose meter
- Rechargeable Li-polymer battery instead of CR2032 battery
- Labeling change due to the above modifications

E. Similarities and Differences between predicate and proposed device

Item	**Predicate device**	**Proposed device**
Brand name	U-RIGHT TD-4252 Blood Glucose Monitoring System (k101631)	Genesis Health Technologies Blood Glucose Monitoring System
Model no	TD-4252	TD-4123
Similarities		
Intended use	It is intended to be used for quantitative measurement of glucose in fresh capillary whole blood (from the finger, palm, forearm and upper-arm) as an aid to monitoring the effectiveness of diabetes control.	Same as predicate
Detection mechanism		
Operating principle	Electrochemical Biosensor technology	Same as predicate
Detection method	Amperometry: measuring a current produced by a chemical reaction	Same as predicate
Specifications		
Temperature compensation	Automatic compensation with built-in thermister	Same as predicate
Sample	0.7 μL	Same as predicate

volume (μL)		
Reaction time (sec)	7	Same as predicate
Measurement range	20-600 mg/dL	Same as predicate
Meter Storage/ Transportation condition	-4 to 140□ (-20□~ 60□), <95% R.H.	Same as predicate
Strip Ejection	Yes	Same as predicate
Functions		
Power saving	Auto turn-off after 3 minutes without action	Same as predicate
Calibration	No coding required	Same as predicate
Alarm Function	4 settings	Same as predicate
Memory feature	450 measurements with day and time	Same as predicate
Test Strip		
Enzyme	Glucose dehydrogenase	Same as predicate
Detection method	Amperometry: measuring a current produced by a chemical reaction	Same as predicate
Blood Volume	0.7 μL	Same as predicate
Reaction time	7 Sec	Same as predicate
Strip Storage/ Transportation condition	35.6°F and 89.6°F (2 ° C and 32° C), below 85% R.H.	Same as predicate
Differences		
Power source :	One CR2032 battery	1x 3.7V Li-polymer battery
Battery recharging function	No	With the battery recharging function through USB
Measurement unit	mg/dL or mmol/L	mg/dL

Test strip indication light	No	Yes
Backlight	No	Yes
Special message	There is a "Ketone?" indicator that shows on the display	No ketone warning symbol provided
Measurement mode	General and QC (quality control)	General, AC, PC and QC (quality control)
QC test stored in memory	No QC results are stored in memory	Yes (User can review QC test in Data record review mode)
Day average	7,14,21,28,60,90 Days	Not provided
Size	89.6(L) x53.8 (W) x16.1 (H)mm	98.5(L) x 58(W) x 15.5(H)mm
Weight	40.6g (Without Battery)	51.4 g (Without Battery)
Data Transmission Capable	No	CDMA module(disabled)

6. Test Principle:
   The detection and measurement of glucose in blood is by an electrochemical biosensor technology using glucose dehydrogenase.

7. Performance Characteristics:
   Genesis Health Technologies Blood Glucose Monitoring System has the same performance characteristics as the predicate device.

   A comparison of system accuracy performance demonstrated that the Genesis Health Technologies Blood Glucose Monitoring System and the U-RIGHT TD-4252 Blood Glucose Monitoring System are substantially equivalent.

   Software verification and validation testing confirmed that the performance, safety and effectiveness of the Genesis Health Technologies Blood Glucose Monitoring System are equivalent to the predicate device.

   The cleaning and disinfection protocol employed by the two systems is validated for the effectiveness of disinfecting HBV, and are robust to cleaning and disinfection procedures after multiple cleaning and disinfection cycles.

8. Conclusion:

   Based on the information provided in this submission, the Genesis Health Technologies Blood Glucose Monitoring System is substantially equivalent to the predicate U-RIGHT TD-4252 Blood Glucose Monitoring System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

TaiDoc Technology Corporation
c/o Linda Ko
3F, 5F, No. 127, Wugong 2nd Rd.
Wugu District
New Taipei City
CHINA (TAIWAN) 24888

SEP 19 2012

Re: k121224
Trade Name: Genesis Health Technologies Blood Glucose Monitoring System, Model TD-4123
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, LFR, JJX
Dated: August 14, 2012
Received: August 23, 2012

Dear Ms Ko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K121224

Device Name: Genesis Health Technologies Blood Glucose Monitoring System, model TD-4123

Indications for Use:

The Genesis Health Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, and the upper-arm. It is intended for use by people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

This system is intended to be used by a single person and should not be shared.

The Genesis Health Technologies test strips are for use with the Genesis Health Technologies meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from fingertips, palm, forearm and upper arm.

The alternative site testing in the Genesis Health Blood Glucose Monitoring System can be used only during steady-state blood glucose conditions.

The Genesis Health Technologies control solutions are for use with the Genesis Health Blood Glucose meter and test strips to check that the meter and test strips are working together properly and that the test is performing correctly.

Prescription Use _____ And/Or Over the Counter Use __X__.

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

9/17/2012

Division Sign-~~Off~~

Office of In Vitro Diagnostic Device

Evaluation and Safety

510(k) k121224